American Association of Exporters and Importers

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
Attention: Docket No. 02N-0278

Re: Comments on the Bioterrorism Act of 2002, Title III; Subtitle A, Section 305 (Registration) and Section 307 (Prior Notice)

The American Association of Exporters and Importers (AAEI) wishes to express its appreciation to the Food and Drug Administration (FDA) for providing an opportunity to review FDA's proposals for implementing the Bioterrorism Act, and we offer the following comments:

Comments on Implementation of Section 305 (Registration)

FDA Registration Is Duplicative

Some of the facilities that will become subject to registration under proposed section 1.225 are already registered with the FDA and/or other federal regulatory agencies. For example, all bonded warehouses have been assigned facility numbers and/or Facilities Information and Resource Management System ("FIRMS") codes. We recommend that FDA consider using the Bureau of Customs and Border Protection (BCBP) FIRMS code, reported on BCBP documents and in BCBP entry data transmissions, as the primary location identifier for imported food items being held in a "secure facility" in accordance with proposed §1.241(e). Further, to minimize confusion, especially about which of one of a facility's multiple registration numbers apply to what types of activities, we strongly recommend that FDA include, on its food facility registration form 3537 or electronic equivalent, optional fields for:

(1) Type of other facility registration number, with checkable options including the above types of registration codes, as well as an option for an "other" type of code, and

(2) The appropriate registration number for each option that is checked.

02N-0278 C157

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Clarification of Status of Air Couriers

In public meetings, FDA officials have said that if food transportation facilities are holding or storing food they will be required to register. FDA should clarify that air courier companies that transport food products are not required to register, because they do not hold or store food products. The essence of air courier service is continuous motion and rapid delivery. Nothing is left sitting long enough that it could reasonably be considered to have been stored.

The regulations should also clarify that simple post-harvesting activities such as cleaning, sorting, and grading should not cause a farm to become subject to registration.

Comments on Implementation of Section 307 (Prior Notice)

Section 1.276 (Food Subject to Prior Notice Reporting) – FDA's finding that in FY 2002 there were only 18 entry lines associated with food in the U.S. mail and 486 entry lines associated with food imported by courier is undoubtedly factually accurate, but almost certainly erroneous. Americans with family ties to other lands undoubtedly receive a much larger number of shipments of food items from abroad, particularly during holiday seasons. At the risk of opening a problem that FDA's proposed rule seems nicely to have finessed, we suggest that FDA squarely address the issue of non-commercial family food shipments by courier and mail and that the final rule add these to the list of exemptions from Prior Notice reporting.

Section 1.277 (Definitions) -

Section 1.277 (c) "country from which the article was shipped" –

FDA proposes to define this term to mean the "country from which the article of food was loaded aboard the conveyance that brings it into the United States." This definition fails to take into account what frequently occurs in the international transportation industry. Both ocean and air carriers routinely use "feeder" vessels/aircraft to move cargo from the country of origin to a "gateway," for transfer to a larger vessel or aircraft, that will transport the cargo to its final destination. The importer/submitter does not necessarily know when and where this may occur. Moreover, ocean vessels frequently discharge containers destined for the U.S. in Canada, where they are transferred to a motor carrier for transport to the U.S.

This proposal, if implemented, will confuse importers and require them needlessly to attempt to obtain the cargo routing from master carriers. As we understand FDA intent, we believe it would be better served by requiring the reporting of the last country in which a product was stored if that is different from the country in which it was produced (the country of origin).

In the discussion of this definition, FDA poses the question of whether this term should include countries of intermediate destination. Consistent with the discussion above, we recommend that as long as a food product is moving on an itinerary consistent with the

bill of lading under which it was shipped, and remains in the custody of the carrier(s) to which is was consigned, reporting of counties of intermediate destination should not be required. Air carriers may transfer shipments of food products from one aircraft to another in an intermediate country prior to bringing them to the U.S.; vessels may call at several foreign ports prior to clearing for the U.S.; food products from countries that do not have major international airports or seaports (including many European countries with relatively sophisticated food safety standards and regulatory systems) may move by truck or rail through intermediate countries prior to being loaded on the carrier that will transport them to the U.S. These are perfectly normal movements but they may not be known to the party submitting the Prior Notice.

On the other hand, if movement of a food product toward the U.S. is interrupted and it comes to rest in a country other than the originating country or the country from which the article was initially shipped, then that country would presumably become the new "country from which the article of food was shipped".

Section 1.277 (e) "originating country" – Importers are currently required to determine and state country of origin of all products, including food products, imported into the United States. This requirement arises under various laws, but progress has been made in the last decade in making origin determinations more transparent and uniform. FDA's breezy dismissal of origin determinations made pursuant to these other long-established laws is ill-considered and unwarranted.

Both FDA and the trade community would be well served if FDA took a closer look at existing origin rules to determine whether there is any reason why they cannot be used for FDA's purposes. In fact, the criteria for determining origin of food products discussed in FDA's February 3 Federal Register notice form the basis for origin rules for food products found in Part 102 of the Customs Regulations. Legally these rules apply only to trade among the NAFTA countries but they are becoming the de facto standard for origin determinations for all trade, because of their transparency and predictability.

If, after examination, FDA finds that there are many products for which the Part 102 rules do not reach an appropriate origin determination, then FDA can proceed as proposed. But if there are no, or only a few, products for which the outcome is inappropriate, FDA should allow existing rules to be applied, with whatever limited exceptions are deemed necessary to avoid inappropriate results. By following this course FDA will be able to obtain consistent and reliable origin information about food products entering the United States. Nothing in the Bioterrorism Act prevents FDA from taking this approach.

Section 1.277 (f) "port of entry" – FDA's proposal carefully explains that the term "port of entry" for FDA's purposes does not have the same meaning that it has under the customs laws, but in fact means the port of arrival of the importing carrier. Since "U.S. port of arrival" is in fact a term already defined in Section 30.8(a) of the U.S. Census Bureau's Foreign Trade Statistics Regulations (15 C.F.R. §30.8(a)), it would seem sensible to substitute that term for "port of entry" in FDA's definitions, rather than attempting to give a new, and inapt, definition to the existing term "port of entry".

Appropriate changes should then be made to the definition of the term "port where entries will be made for customs purposes".

Section 1.286 (When Must the Prior Notice be Submitted to FDA) – FDA proposes that all information required by the Prior Notice regulations be submitted to FDA not later than noon of the calendar day before the day the article of food will arrive at the border crossing. FDA correctly notes two cases in which this requirement appears to be problematic:

(1) Imports of fresh produce from NAFTA countries - It is not clear, or perhaps it is unfortunately all too clear, what effect the Prior Notice will have on imports of fresh produce from Canada and Mexico. Much of this produce, particularly produce from Mexico, arrives in the United States shortly after being picked in the field. The effect of the proposed rule is to require either that the produce be picked and left to sit for a day, or that an importer file a Prior Notice a day in advance, based on a best guess of what will be arriving, and then correct that guess not less than two hours prior to arrival. It can easily be foreseen that virtually every shipment of fresh produce into the United States from Mexico and Canada will require both filing a Prior Notice and an amendment to the Prior Notice.

Moreover, a significant part of this trade consists of shipment of fresh produce on consignment. There is no U.S. purchaser of these goods at the time they enter the U.S., and often the designation of a U.S. customs broker to make entry occurs when the shipment arrives. FDA's proposed rule appears to make no accommodation for this trade.

This adds significant red tape and administrative cost to an established trade that has been carried on safely for over a century with substantial benefits for the U.S. public. It will be unfortunate if a way cannot be found to allow FDA to deal differently with this situation.

(2) Imports of perishable foods by air – Imports of fresh fish and other perishable, high-value food products that supply the upscale restaurant and gourmet foods markets often arrive by air. Although some information about these shipments can be transmitted to FDA by noon of the day prior to arrival, much of the information required to satisfy the Prior Notice requirement is not available until shortly before delivery to the importing carrier. In almost every case, information submitters will be required to send a Prior Notice based on a best guess and subsequently to file changes (if allowed under Section 1.289) or to cancel the initial Prior Notice and submit a new one. In other words, Section 1.286 as proposed effectively mandates redundant filing of Prior Notices, wasting the time and resources of notice filers and the FDA.

FDA gives as the reason for requiring Prior Notice not later than noon of the day prior to arrival the fact that "FDA does not have staff located at or near all of the 250 ports" where food products enter the U.S. Since "FDA cannot limit ports at which food

products may be imported" it needs approximately one day's prior notice so that it can "send inspectors to any port in the United States if necessary".

This places the entire Prior Notice proposal on a worst case basis. Notwithstanding that the great majority of food imports may enter through ports at which FDA has inspectional personnel, the Prior Notice Requirement presumes that in all instances in which inspection is indicated FDA staff will need a day to plan and complete travel. FDA should revise its proposal to provide for Prior Notice to be sent not later than two hours prior to arrival. If the shipment is destined for a port at which FDA has inspectional personnel, two hours advance notice will be adequate to allow FDA to screen the information and determine whether an examination is required. If the shipment is destined for a port at which FDA is not present and FDA wishes to inspect it, two hours advance notification will allow FDA to notify the BCBP to hold the shipment until FDA inspectors can arrive.

FDA and the BCBP are part of the same government. It is not necessary to force all food importers to file a notification a day in advance in order for that government to have adequate control over food shipments that arrive at ports with no FDA presence.

Section 1.288 (What information must be submitted) –

(c) ACS entry line numbers are not available at noon on the calendar day prior to arrival because under the Customs Regulations there is no requirement to file an entry at that time.

Quantity information is seldom needed for risk assessment and should not be required in the Prior Notice. Is 200 kilograms of fresh fish or yellow onions more dangerous than 160 kilograms? Are 2000 cases of canned peas more hazardous than 1800 cases? Requiring information that may change subsequent to filing the initial Prior Notice and that rarely if ever is relevant to risk creates an unnecessary burden by forcing avoidable redundant filing of amendments to Prior Notices. If FDA can identify circumstances in which quantity relates to risk, it should require quantity information in those cases only, not for the great majority of cases in which quantity is irrelevant to risk.

(g) Identities of growers, if known is vague, unnecessarily burdensome, and almost certainly of little value if identifying bioterrorism risks. It leaves unclear what obligation a filer has to acquire knowledge of the identities of growers if the filer is a consolidator of fresh produce shipments or a food processor who does not ordinarily have that information; it fails to take cognizance of the fact that most of the world's food growers are not agribusinesses on the scale of Tyson Foods, but millions of family farms; and it will be of little use for bioterrorism screening unless FDA is contemplating creating risk profiles for millions of growers.

We agree with the suggestion made in the February 3 notice that FDA has the authority to forego requiring identification of individual growers where multiple growers are involved and may instead require the identity of the consolidator or processor.

Section 1.289 (Changes to Prior Notice) –

In those cases where an amendment to a previously submitted Prior Notice is not permitted and a new Prior Notice is required, does the deadline applicable to amendments (two hours prior to arrival of the shipment) apply to the substituted Prior Notice, or is the new Prior Notice subject to the original deadline (noon of the day prior to arrival)?

In the "Highlights of This Rule" section on page 5429 of the February 3 notice, FDA states that quantity may be amended. However, proposed §1.289 on page 5462 of the notice provides that"[a]fter a prior notice has been submitted to FDA, it may only be changed as set out in § 1.290 which relates to product identity amendments or § 1.294 which relates to arrival updates." Although, as noted above, we question whether quantity information is needed for bioterrorism risk assessment, if FDA decides to retain it as part of the Prior Notice requirement, we recommend that FDA clarify that quantity information can be amended. If FDA intended that quantity be a part of product identity, it should clarify that. The notice treats product identity and quantity as separate information items.

Coordination of FDA and BCBP anti-terrorism programs

In the aftermath of September 11, Congressional committees vied with each other to pass the first and most stringent anti-terrorism legislation. Coordinated action is not a forte of popular legislatures, but it should be of government executive agencies. Nothing in the various statutes that BCBP and FDA must implement prevents them from coordinating implementation.

Almost all of the information that FDA seeks for bioterrorism screening is proposed to be collected by the BCBP for its terrorism screening program. The uncoordinated, simultaneous application of separate BCBP and FDA information collection and screening programs would be burdensome, costly, and not optimally effective. If, as we understand, FDA intends to create a new Prior Notice electronic reporting system with no checks and edits for filers, it is likely that FDA's bioterrorism program will be consumed by reconciliation of clerical errors.

Coordination Within FDA

Internally, FDA should work toward merging the 801(a) (food wholesomeness) and 801(m) reporting and screening processes. Fundamentally, both processes are aimed at determining whether a particular food shipment is safe and may be admitted into the U.S. The fact that the nature and origin of risks is different does not constrain FDA to establish duplicative processes.

In addition to coordinating reporting and screening processes, FDA should give incentives to importers that reduce risks by thorough internal security regimes and adherence to security standards set forth by FDA, BCBP, or other agencies dealing with

security. These incentives could include shorter advance reporting requirements or authorization to use blanket Prior Notices for repetitive shipments. Both of these incentives appear to be allowed by the statute.

Finally, we would like in our comments to incorporate by reference comments filed by the Foreign Trade Association of Southern California (FTA), which address specific local factors that FDA should take into account.

Again, AAEI is grateful to FDA for offering us this opportunity to comment on implementation of the Bioterrorism Act, and we stand ready to assist FDA in finding practical solutions to the challenge of maintaining a high level of food safety for the American people.

Sincerely,

John P. Simpson
President